

510(k) SummaryFukuda Denshi DynaScope Model DS-7000 Series
Patient Monitor
(Model: DS-7000/7000M/7210/7210M)

MAR 19 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 870.92.

The assigned 510(k) number is: _____.

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- **Date Prepared:** December 12, 2008

Device Name:

- **Proprietary Name :** Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor
(Model: DS-7000/7000M/7210/7210M)
- **Common Name:** Patient Monitor
- **Product Code:** MHX
- **Regulation Number:** 21 CFR Part 870.1025
- **Class:** II
- **Review Panel:** Cardiovascular

510(k) Summary

Fukuda Denshi DynaScope Model DS-7000 Series
Patient Monitor
(Model: DS-7000/7000M/7210/7210M)

Legally Marketed Device:

Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor (K081891)

In addition, CO₂ measurement optional function of the DS-7210/7210M of the DS-7000 Series utilizes an OEM manufactured module (K060065) and a CO₂ Sensor (K042601) that have received separate clearance from the FDA as follows:

The CO₂ measurement system used in the DS-7210/7210M is the same as that used in the Oridion Medical 1987 Ltd. model "Capnostream20" cleared under 510(k) # K060065.

The CO₂ measurement sensor connected to the DS-7210/7210M is the same as the Respironics Novamatrix, LLC. model "Capnostat 5 Mainstream CO₂ Sensor" cleared under 510(k) # K042601.

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Patient Monitor
(Model: DS-7000/7000M/7210/7210M)

Description:

The Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) is meant to acquire and monitor physiological signals from patients. The system is design to be used in ICU, CCU, OR, ER, or Recovery areas of the hospital or clinic. An optional Battery Pack operation allows the DS-7210/7210M to be used to monitor patients during intra-hospital transport. Patient ages from neonates to adults can all be monitored. Waveforms, numeric and trend data from these patients are available to the clinician on the systems display or may be printed on the system's recorder.

The DS-7000 Series Patient Monitor allows for the monitoring of ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO₂), plethysmograph, temperature, invasive blood pressure (IBP), and cardiac output. This subject modified DS-7000 Series Patient Monitor extended the NIBP measurement target populations from adult and pediatric to adult, pediatric, and neonatal and the DS-7210/7210M of the DS-7000 Series includes ECG 12 Lead monitoring.

The DS-7000/7000M of the DS-7000 Series Patient Monitor allows for the monitoring of carbon dioxide concentration (CO₂), nitrous oxide concentration (N₂O), oxygen concentration (O₂), and anesthetic agent concentration (AG), which utilizes Criticare Systems technology (K012059), by using the option Multigas Unit (MGU-701/MGU-702). And, by using the option Unit (HU-71/HU-72/HU-73), invasive blood pressure (up to 6 channels), cardiac output, temperature (up to 3 channels) can be additionally monitored. No new functions for the options are being added and are not the subject of this submission for the DS-7000/7000M.

This subject modified DS-7210/7210M of the DS-7000 series Patient Monitor allows for the monitoring of carbon dioxide concentration (CO₂), which utilizes Oridion Medical 1987 Ltd. technology "Microstream[®]" (K060065), by using the option CO₂ measurement unit (MGU-722). Or, by using the option Mainstream CO₂ interface Unit (MGU-721), the Capnostat 5 Mainstream CO₂ Sensor (K042601) manufactured by Respironics Novamatrix, LLC. is allowed to connect to the DS-7210/7210M with serial communication protocol for CO₂ monitoring. And, by using the option Unit (HU-71/HU-72/HU-73), invasive blood pressure (up to 5 channels), cardiac output, temperature (up to 3 channels) can be additionally monitored.

For the SpO₂ measurement monitoring, the DS-7000 utilizes Nellcor technology (K021090) and the DS-7000M utilizes Masimo one (K033296). No new

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(Model: DS-7000/7000M/7210/7210M)

functions for SpO₂ measurement are being added and are not the subject of this submission. This subject modified DS-7210/7210M has the same feature.

The DS-7000 Series Patient Monitor is a self contained monitor which includes a 12.1 inch TFT color LCD display which can display up to 12 (for DS-7000/7000M) or 14 (for DS-7210/7210M) waveforms and up to 20 (for DS-7000/7000M) or 16 (for DS-7210/7210M) numeric displays. Input operation is performed by the touch screen panel, 5 fixed keys (only DS-7000/7000M), or infrared remote-control command (optional). Additional standard features of the DS-7000 Series Patient Monitor include the DS-LAN II connection, which is a proprietary network system based on an Ethernet LAN (K970585), through either a built in Ethernet LAN or external telemetry transmitter (the Fukuda Denshi DS-5000 series telemetry model HLX-501/561, K980728) connection for connection to the Fukuda Denshi Central Station Monitors, a built-in dot matrix thermal printer that can print up to 3 wave forms simultaneously, and an alarm indicator feature on the top of device that alerts to alarm conditions.

The DS-7000/7000M of the DS-7000 Series is small and lightweight at 9.0 kg. The physical dimensions of the device are 324mm (W) x 260mm (H) x 179mm (D). The option Multigas Unit (MGU-701/MGU-702) weight is 1.8 kg. The physical dimensions of the device are 248mm (W) x 138mm (H) x 82mm (D). No weight and physical dimensions are being changed and are not the subject of this submission for the DS-7000/7000M.

The subject modified DS-7210/7210M weight is 9.9 kg. The physical dimensions of the device are 310mm (W) x 351mm (H) x 245mm (D). The option CO₂ measurement Unit (MGU-722) weight is 260g and Mainstream CO₂ interface unit (MGU-721) weight is 200g. The both physical dimensions of the device are 141.5mm (W) x 41mm (H) x 79mm (D).

For the DS-7000 Series option Unit (HU-71/HU-72/HU-73) weight is 180g. The physical dimensions of the device are 37mm (W) x 99 mm (H) x 90 mm (D). No weight and physical dimensions are being changed and are not the subject of this submission.

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Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M)

Statement of Intended Use:

The Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. These patients; adult, pediatric, and neonate, may be located in a hospitals ICU, CCU, OR, ER, recovery or other critical care area. The DS-7000 Series can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician.

The availability of the DS-LAN II connection, through either a built in Ethernet LAN or external telemetry transmitter, allows remote monitoring when combined with the Fukuda Denshi Central Station Monitors. An option battery operation of the 7210/7210M allows a patient to continue to be monitored during intra-hospital transport.

Parameters such as ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO₂), pulse wave, temperature, invasive blood pressure (IBP), cardiac output, carbon dioxide concentration (CO₂), nitrous oxide concentration (N₂O), oxygen concentration (O₂), and anesthetic agent concentration (AG) may be monitored individually or in any grouping required by the clinician.

The Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor is not recommended for home use, when it has not been ordered by a physician.

Technological Characteristics:

The Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) incorporates the identical technology as the predicate devices. The device provides a means with interfacing with a patient, collecting parameter specific physiological data and processing the data for alarm generation, display of numeric values and waveforms at bedside or at a central monitoring station.

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(Model: DS-7000/7000M/7210/7210M)

The technology characteristics of the DS-7000 Series Patient Monitor do not affect the safety or efficacy of the device. Any safety issues raised by a software control medical device are either the same issues already addressed by the predicate devices or are addressed the system hazard analysis, or in the system validation.

Testing:

The Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) has been subjected to extensive safety, environmental and performance testing. Final testing for the device included various performance test for the device designed to insure that all functional and performance specifications were met. Additionally the device was host tested at the previously noted OEM engineering test facility to insure that performance and functional specifications for their supplied module were met.

The DS-7000 Series has also been tested to assure compliance to the requirement of various published standards including the following:

- General safety standards
UL60601-1(IEC60601-1), IEC60601-1-1, IEC60601-1-4, IEC60601-1-8, ISO 14971
- Individual standards
ANSI/AAMI EC-13, ANSI/AAMI EC-53, ANSI/AAMI EC-57, ANSI/AAMI SP-10, IEC60601-2-27, IEC60601-2-30, IEC60601-2-34, IEC60601-2-49, EN12470-4, EN980, ISO 9919, ISO 21647
- EMC standards
IEC 60601-1-2

Conclusion:

In conclusion, drawing from laboratory testing, validation and risk Analysis, the Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) demonstrates that this device is as safe and effective and performs as well or better than the legally marketed predicate devices, the Fukuda Denshi Model DS-7000/7000M Patient Monitor 510(k) # K081891.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 19 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fukuda Denshi USA, Inc.
c/o Mr. Doug Blakely
Director – Regulatory Affairs
17725 NE 65th St. Building C
Redmond, WA 98052

Re: K083697

Fukuda Denshi DynaScope Model DS – 7000 Series Patient Monitor

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Regulatory Class: Class II (Two)

Product Code: MHX, (DRT, DXN, DSK, DQA, BZQ, CCK and FFL)

Dated: January 26, 2009

Received: January 26, 2009

Dear Mr. Blakely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

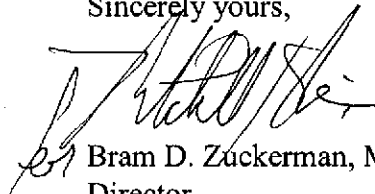
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083697

Device Name: Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor

Indications For Use:

Use of the Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) is indicated in those situations where observation of one or more of the following parameters on an individual patient may be required. ECG (waveform, heart rate, ST-Level and ventricular arrhythmias), respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO₂), pulse wave, temperature, invasive blood pressure (IBP), cardiac output, carbon dioxide concentration (CO₂), nitrous oxide concentration (N₂O), oxygen concentration (O₂), and anesthetic agent concentration (AG). The target populations of the system are adult, pediatric, and neonatal patients with the exception of the ST segment and arrhythmia analysis, for which the target populations are adult and pediatric only. These observations can include an audible and visual alarm if any of these parameters exceed values that are established by the clinician. The observations may include the individual or comparative trending of one or more of these parameters over a period of up to 24 hours. The DS-7000 Series Patient Monitor is indicated in situations where an instantaneous display of waveform, numeric and trended values is desired. The DS-7000 Series Patient Monitor is also indicated where a hard copy record of the physiological parameters, the alarms conditions or the trended values may be required.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH/Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Cardiovascular Devices

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